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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,001

06/13/2005

John Jenkins

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EXAMINER

LAU, JONATHAN S

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/511,001	<b>Applicant(s)</b> JENKINS, JOHN	
	<b>Examiner</b> Jonathan S. Lau	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

This Office Action details a Restriction Requirement and an Election of Species Requirement.

### ***Response to Preliminary Amendment***

The preliminary amendment to the claims filed on 12 Oct 2004 does not comply with the requirements of 37 CFR 1.121(c) because "Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application." Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims.* Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing.* All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required.* All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim

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having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of "canceled" or "not entered."

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as "canceled" will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a "new" claim with a new claim number.

The preliminary amendment to the claims filed on 12 Oct 2004 does not comply with the requirements of 37 CFR 1.121(c), and has not been entered. Accordingly, Examiner has acted on the set of pending claims 1-19 presented in the preliminary amendment and also 20-31 as originally filed.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19, drawn to a method of administering chemotherapy, comprising a first agent that attenuates Topoisomerase I (Topo I) activity and the use of a second agent that inhibits Heat Shock Protein 90 (HSP90) activity. (See Examiner's Note)

Group II, claim(s) 20 and 21, drawn to a delivery system for use in a gene therapy technique comprising a first DNA molecule encoding for a protein which directly or

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indirectly attenuates Topoisomerase I activity and a second DNA molecule encoding for a protein which directly or indirectly inhibits Heat Shock Protein 90 activity and the use of said delivery system for the manufacture of a medicament. (See Examiner's Note)

Group III, claim(s) 22, drawn to method of treatment comprising the use of said delivery system. (See Examiner's Note)

Group IV, claim(s) 23-28, drawn to a method of screening a first and a second compound comprising exposing said compounds to Topoisomerase I and evaluating whether or not said compounds bind thereto, exposing said compounds to Heatshock Protein 90 and evaluating whether or not said compounds bind thereto and selecting a first and second compound.

Group V, claim(s) 29 -31, drawn to an *in vitro* method for diagnosing comprising detecting the level of activity or expression levels of Heat Shock Protein 90 and Topoisomerase I from a sample of cells from said subject and comparing the level of activity or expression levels of Heat Shock Protein 90 and Topoisomerase I in said sample relative to activity expression levels of Heat Shock Protein 90 and Topoisomerase I from a non-cancerous sample.

**Examiner's Note:**

Claims 21-22 as currently pending recite "use" claims. Examiner has interpreted claims 1-19 as drawn to a method of treatment using said first and second agent. Examiner has interpreted claim 21 as a method of making a medicament comprising said delivery system. Examiner has interpreted claim 22 as a method of using said medicament comprising said delivery system.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The common feature between the inventions of Groups I-V is interaction with Topo I and HSP90. However, such a feature is a known concept. Placke et al. (US Patent Application Publication 2001/0038827, published 08 Nov 2001, cited in PTO-892) discloses one embodiment of treating a patient with geldanamycin (page 3 paragraph 21), an agent that inhibits HSP90 activity, and one embodiment of treating a patient with 9-aminocamptothecin (page 3, paragraph 23), and agent that attenuates Topo I activity, and envisions the use of the embodiments in combination chemotherapy treatment (page 23, paragraph 177). Therefore interaction with Topo I and HSP90 is not the special technical feature of a single general inventive concept.

***Election of Species Requirement***

If Applicant elects the invention of **Group I**, Applicant is further required to elect from both the following **first** and **second** species elections.

If Applicant elects the invention of **Group III**, Applicant is further required to elect from the following **second** species election.

This application contains claims directed to more than one **first** species of methods comprising use of a first and second agent and **second** species of condition to be treated of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**First Species Election:**

One example of a specie of methods comprising use of a first and second agent is as follows:

The method comprising use of the first agent camptothecin (disclosed in claim 4) and the second agent geldanamycin (disclosed in claim 10).

**Second Species Election:**

Examples of species of condition to be treated are as follows, disclosed in claim 15, 17-19:

bowel cancer,  
small cell and non-small cell lung cancer,  
head and neck cancer,  
breast cancer,

bladder cancer,  
malignant melanoma,  
neuroblastoma,  
leukaemias,  
lymphomas,  
antibacterial treatments,  
antifungal treatments,  
antiparasitic treatments,  
the treatment of AIDS/HIV,  
the treatment of multiple sclerosis,  
the killing and inhibition of proliferation of any organism other than by  
antibacterial, antifungal and antiparasitic treatments, and  
prophylactic treatment.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election. Applicant is cautioned that election of a subgenus, such as electing the subgenus of "cancer" for the second species election of condition to be treated, will be considered non-responsive.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1-9 and 13-19 are generic to the first agent and claims 1-3 and 9-19 are generic to the second agent. Claims 1-18 and 22 are generic to the condition to be treated.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: The common feature between the inventions of Groups I-V is interaction with Topo I and HSP90. However, such a feature is a known concept. Placke et al. (US Patent Application Publication 2001/0038827, published 08 Nov 2001, cited in PTO-892) discloses one embodiment of treating a patient with geldanamycin (page 3 paragraph 21), an agent that inhibits HSP90 activity, and one embodiment of treating a patient with 9-aminocamptothecin (page 3, paragraph 23), and agent that attenuates Topo I activity, and envisions the use of the embodiments in combination chemotherapy treatment (page 23, paragraph 177). Therefore interaction with Topo I and HSP90 is not the special technical feature of a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does



not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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